



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
FAX: 425-483-4996

January 31, 2005

**VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

In reply refer to Warning Letter SEA 05-13

Anna L. Swain, Vice President
Wax Orchards, Inc.
22744 Wax Orchard Road
Vashon, Washington 98070

WARNING LETTER

Dear Ms. Swain:

The U.S. Food and Drug Administration (FDA) inspected your firm, located at 22744 Wax Orchard Road, Vashon, Washington 98070, on September 21, 2004. During the inspection, copies of product labels were collected for a number of your products, including "APPLE APPLE Only Fruit™ Butter," "RASPBERRY SYRUP," "FUDGE FANTASY," and "Ap'le Berry Juice." Based on the labels for these products, we have determined that they are misbranded under section 403 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § 343). In addition, during the inspection, our investigator documented multiple deviations from FDA's Juice HACCP Regulation, located in Part 120 of Title 21 of the Code of Federal Regulations (21 CFR Part 120), for your apple juice products. In accordance with 21 CFR 120.9, failure of a processor to have and implement a HACCP plan that complies with this section or otherwise operate in accordance with the requirements of this part renders the juice products adulterated within the meaning of Section 402(a)(4) of the Act (21 U.S.C. § 342(a)(4)). The specific violations are identified and explained below. You can find the Act and FDA's regulations, including the Juice HACCP Regulation, through links on FDA's Internet homepage at <http://www.fda.gov>.

The labeling deviations for your "APPLE APPLE Only Fruit™ Butter" product are as follows:

1. Your "APPLE APPLE Only Fruit™ Butter" product is misbranded under section 403(r)(1)(A) of the Act because it bears the nutrient content claim "Low-Calorie," which is not made in accordance with 21 CFR 101.60(b)(2). Section 101.60(b)(2)(i)(B) permits a "low calorie" claim on the label or in the labeling of small serving size foods (i.e., foods with a reference amount customarily consumed (RACC) of 30 grams (g) or less or two tablespoons or less) when the

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food does not provide more than 40 calories per RACC and per 50 g. Your "APPLE APPLE Only Fruit™ Butter" product is labeled as having 22.5 calories per 15g; therefore, it does not meet the requirements established by 21 CFR 101.60(b)(2)(i)(B) to make a "low calorie" claim because it provides more than 40 calories per 50 g of the food.

2. This product is further misbranded under section 403(r)(1)(A) of the Act because the label bears the nutrient content claim "High-fiber," which is not made in accordance with 21 CFR 101.54(b)(1). Section 101.54(b)(1) permits a "high fiber" claim on the label or in the labeling of foods provided that the food contains 20% or more of the Daily Reference Value (DRV) for fiber per RACC. This product is labeled as having 2% of the DRV for fiber per tablespoon; therefore the product does not meet the requirements established by 21 CFR 101.54(b)(1) to make a "high fiber" claim.

You should take prompt action to correct these violations and prevent their recurrence. Failure to make prompt corrections could result in regulatory action without further notice. For instance, FDA may seize your violative products and/or enjoin your firm from operating.

It is essential that you respond in writing within fifteen (15) working days from your receipt of this letter. Your response should outline the specific actions you are taking to correct the deviations noted above. If corrective actions cannot be completed within fifteen working days, state the reason for your delay and the time within which you will correct any remaining deviations.

Additional Labeling Deviations

1. We advise that the "Nutrition Facts" panels for "APPLE APPLE Only Fruit™ Butter" and "FUDGE FANTASY" do not declare the values for certain nutrients in the manner required by 21 CFR 101.9(c). Specifically, the nutrition labeling for your "APPLE APPLE Only Fruit™ Butter" product does not declare sodium, dietary fiber, and sugars in the manner required by section 101.9(c). The nutrition labeling for your "FUDGE FANTASY" product does not declare total fat, total carbohydrate, dietary fiber, and protein in the manner required by section 101.9(c). For example, dietary fiber must be declared to the nearest gram, except that if a serving contains less than one gram, declaration of dietary fiber is not required or, alternatively, the statement "Contains less than 1 gram" or "less than 1 gram" may be used; if the serving contains less than 0.5 gram, the content may be expressed as zero (21 CFR 101.9(c)(6)(i)).
2. The nutrition labels for "APPLE APPLE Only Fruit™ Butter," "FUDGE FANTASY," and "RASPBERRY SYRUP" must declare carbohydrate as "Total carbohydrate" or "Carbohydrate, total," instead of "Total Carbohydrates" (21 CFR 101.9(c)(6)).

3. The labels for "APPLE APPLE Only Fruit™ Butter," "RASPBERRY SYRUP," and "FUDGE FANTASY" include the statement "(from conc. fruit juice)" after the declaration of sugars in the Nutrition Facts panel. We advise that this statement is intervening and should be removed (21 CFR 101.2(e)).
4. The "Nutrition Facts" panels for "APPLE APPLE Only Fruit™ Butter," "RASPBERRY SYRUP," and "FUDGE FANTASY" must be set off in a box, in accordance with 21 CFR 101.9(d)(1)(i).
5. Generally, the ingredients required to be in the ingredient statement must be declared by a specific common or usual name, and not a collective (generic) name, in accordance with 21 CFR 101.4(a)-(b). The ingredient statement on your "Ap'le Berry Juice" incorrectly declares "Berry Juices" instead of the specific type of berry juice(s) contained in the product (e.g., "raspberry juice"). We also note that the ingredient list for "APPLE APPLE Only Fruit™ Butter," "RASPBERRY SYRUP," and "FUDGE FANTASY" do not identify each of the ingredients by their specific common or usual name in descending order of predominance by weight (21 CFR 101.4(a)). For example, if the ingredients identified as "conc. pear, peach pineapple, grape" are concentrated fruit juices, they must be individually declared as concentrated fruit juices (e.g., "pear juice concentrate," "peach juice concentrate," etc.).

Juice HACCP Deviations

1. You must have and implement a written Hazard Analysis and Critical Control Point (HACCP) plan to control any food safety hazards that are reasonably likely to occur during processing, to comply with 21 CFR 120.8(a). However, your firm does not have a HACCP plan for your "Apple Apple Juice," "Ap'le Berry Juice," "Pasteurized Spiced Apple Juice," and "Ginger Apple Juice" products to control the food safety hazards of pathogens. Furthermore, your firm does not have a written Hazard Analysis to determine whether there are food safety hazards that are reasonably likely to occur for each type of juice that you process, and to identify control measures that you can apply to control those hazards, in accordance with 21 CFR 120.7.
2. You must have sanitation standard operating procedure (SSOP) records that, at a minimum, document monitoring of sanitation conditions and practices during processing and corrections of conditions and practices that do not conform to appropriate provisions in 21 CFR Part 110, to comply with 21 CFR 120.6(c). However, your firm does not maintain SSOP records for condition and cleanliness of food contact surfaces; prevention of cross contamination from insanitary objects to food, food packaging material, and other food contact surfaces; maintenance of hand washing, hand sanitizing, and toilet facilities; protection of food, food packaging material, and food contact surfaces from

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adulteration; proper labeling, storage, and use of toxic compounds; control of employee health conditions that could result in the microbial contamination of food, food packaging materials, and food contact surfaces; and exclusion of pests from the food plant (see 21 CFR 120.6(a)).

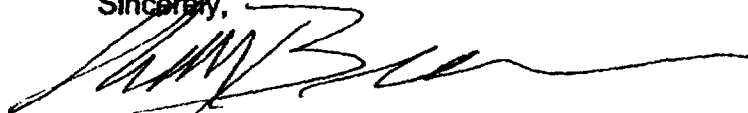
We encourage you to make the necessary improvements as soon as possible. However, if you disagree with our preliminary assessment of deviations from the Juice HACCP Regulation, you should explain how your system identifies hazards and implements controls in a manner that the agency should regard as complying with the regulation. We understand that HACCP systems may be uniquely tailored to meet the circumstances of the individual processor and that there may be more than one right way to control hazards.

The above violations are not meant to be an all-inclusive list of deficiencies for these products or their labeling or any other product your firm manufactures or labels. It is your responsibility to ensure that all of your products comply with the laws and regulations enforced by FDA.

For the additional labeling deviations and Juice HACCP deviations identified above, please respond in writing within thirty (30) calendar days from your receipt of this letter and identify the specific steps you have taken or intend to take to correct the noted deviations.

Please send your response(s) to the U. S. Food and Drug Administration, 22201 23rd Drive SE, Bothell, Washington 98021, Attention: Lisa M. Althar, Compliance Officer. If you have questions regarding any issue in this letter, please contact me at (425) 483-4940.

Sincerely,

A handwritten signature in black ink, appearing to read 'Charles M. Breen', written over a horizontal line.

Charles M. Breen
District Director

cc: WSDA with disclosure statement